U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

E.A. Beck & Co. 12/14/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L
16-11

December 14, 2010

Carol A. Swickard
President
E. A. Beck & Co.,
657 West 19th Street, Suite E
Costa Mesa, California, 92627-2777

Dear Mr. Swickard:

During an inspection of your firm located at 657 West 19th Street, Suite E, Costa Mesa, California, conducted between August 10, 2010 through August 25, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Erich Arch Bar **(b)(4)** Mathieu for Wire and Elastic Style Ligature Ties, and Mathieu for Elastic Style Ligature Ties which are finished devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

The inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. These violations include, but not limited to the following:

1. Failure to establish and maintain written procedures for implementing corrective and preventive action procedures, as required by 21 CFR 820.100(a). For example, your firm has no corrective and preventive action procedures.

2. Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm has no written procedures to ensure that all purchased or otherwise received products and services conform to specified requirements.

3. Failure to ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). For example, the heat sealing process, used to seal product packing, has not been validated for the dental pliers (Mathieu, Reference numbers 500-081 and 500-083) and all other Class I

devices that use this process.

4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm has no procedures for receiving, reviewing, and evaluating complaints.

5. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, your firm has no acceptance activities for the Erich Arch Bars (Catalog #201-001) and dental pliers (Mathieu, Reference numbers 500-081 and 500-083. Also, your firm has not established a sampling plan for the evaluation of products during incoming inspection of the Erich Arch Bars (Catalog #201-001).

6. Failure to validate, for its intended use, computers or automated data processing systems used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, your firm has not validated the software used for generating product labels.

7. Failure to maintain Device Master Records (DMRs), as required by 21 CFR 820.181. For example, the firm has no DMRs for the Erich Arch Bars (Catalog #201-001) and dental pliers (Mathieu, reference numbers 500-081 and 500-083).

8. Failure to establish and maintain procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184. For example, your firm has no DHRs for the Erich Arch Bars (Catalog #201-001) and dental pliers (Mathieu, Reference numbers (500-081 and 500-083).

9. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR 820.120. For example, your firm has no procedures established for generating labels for the devices.

Our inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Specifically, your firm does not have any written MDR procedures as required by 21 C.F.R. Part 803.

Our inspection also revealed that the Erich Arch Bars and the wires associated with the devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html[1]. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

The Erich Arch Bar **(b)(4)** and Mathieu for Wire and Elastic Style Ligature Ties, and Mathieu for Elastic Style Ligature Ties are also misbranded under section 502(f)(1) of the Act because the labeling fails to bear adequate directions for the uses for which they are being offered. Specifically, there is no statement in the label of whether or not the Erich Arch Bar **(b)(4)** requires sterilization prior to use and the recommended sterilization modality for the Mathieu for Wire and Elastic Style Ligature Ties, and Mathieu for Elastic Style Ligature Ties is not documented in the labeling, as required by 21 CFR 801.5(g).

In addition, The Erich Arch Bar **(b)(4)** is misbranded under section 502(o) of the Act (21 U.S.C. § 352(o)), in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under 21 U.S.C 360; was not included in a list required by 21 U.S.C. 360(j); or a notice or other information respecting the device was not provided to the FDA as required by 21 U.S.C. 360(k).

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the following address:

Blake Bevill
Director, Compliance Branch

U.S. Food and drug Administration
19701 Fairchild, Irvine, California 92612-2506

If you have any questions about the content of this letter please contact: Ms. Mariza Jafary, Compliance Officer at 949-608-2977.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of th inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

/S/

Alonza E. Cruse
District Director
Los Angeles District

cc: Ingerborg B. Small
California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue – MS 7602
Post Office Box 997435
Sacramento, California 95899-7435

Links on this page:

1. http://www.fda.gov/cdrh/devadvice/3122.html